SEP - 8 2011

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ATTACHMENT 3

SECTION 5: 510(K) Number; K112209

510(K) SUMMARY

Requirement	Information
510(K) Owner	Avail Medical Products Inc.
Address	5950 Nancy Ridge Road, Ste.500 San Diego CA 92121 USA
Telephone # Fax #	858-457-1988 858-558-7264
Contact Person	Steven A.Howell
Summary Preparation Date	August 10, 2011
Proprietary Name	Sterile, Water Filled Syringe
Common Name	Pre-filled Catheter Inflation Syringe
Classification Name	Urological Catheter & Accessories (21 CFR876.5130) Product Code KNY
Legally marketed predicate device	Pre Filled Catheter Inflation Syringe (K90121)
Device Description	A sterile, water filled, single patient use syringe designed for catheter inflation only. Not for injection. The syringes are bulk packaged for sale to customers for inclusion in urological kits. The syringes are not marketed or sold as separate devices from urological kits. The intended use of the device is to provide a sterile liquid for Foley catheter inflation after insertion. The syringe cap is removed, the syringe luer tip connects directly to the catheter valve. The sterile water is expressed to inflate the catheter. The syringe is disconnected and discarded after use.
Intended Use of the Device	Pre-filled catheter inflation syringe for catheter balloon inflation. The device is substantially equivalent to the predicate device.

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Requirement	Information
Technological Characteristics of the device compared to the predicate device	The new device is substantially equivalent to the predicate device. The new device has the same technological characteristics as the predicate device. Both devices utilize polypropylene materials of construction with medical grade, butyl rubber plunger tips and caps. Both devices are terminally gamma sterilized and bulk packaged for inclusion in customers urological kits.
Assessment of Non Clinical Tests used to support substantial equivalence	Sections 2 (standards testing), 15 (biocompatibility) and 19 (performance testing) of this 510(k) submission identify the non clinical tests and results used to support substantial equivalence to the predicate device
Assessment of Clinical Tests used to support substantial equivalence	Not Applicable. No Clinical tests were conducted
Conclusion of tests used to support substantial equivalence to the predicate device	A comparison of the acceptable results of the testing completed on the new device and the results of testing of the predicate device support a claim of substantial equivalence between the new device and the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Steven A. Howell
Senior Director - Quality Assurance
Avail Medical Products Inc.
5950 Nancy Ridge Road, Suite 500
SAN DIEGO CA 92121

SEP - 8 2011

Re: K112209
Trade/Device Name: Avail Sterile Water Filled Syringe
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: August 17, 2011
Received: August 19, 2011

Dear Mr. Howell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2 (continued)

SECTION 4:

INDICATIONS FOR USE

510(k) Number: K112209

Device Name: Avail Sterile Water Filled Syringe

Indications For Use:

The Avail Sterile Water Filled Syringe is intended to be used to provide a sterile liquid for catheter inflation after insertion.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ or Over-the-Counter Use _____ (Per 21 CFR 801.109)

For Professional Use Only (Medical Health Provider) _____

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112209